LEGISLATIVE SERVICES AGENCY OFFICE OF FISCAL AND MANAGEMENT ANALYSIS

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FISCAL IMPACT STATEMENT

LS 6257 NOTE PREPARED: Dec 2, 2005

BILL NUMBER: HB 1048 BILL AMENDED:

SUBJECT: Mercury in Vaccines.

FIRST AUTHOR: Rep. Bell BILL STATUS: As Introduced

FIRST SPONSOR:

FUNDS AFFECTED: X GENERAL IMPACT: State & Local

 $\begin{array}{c} \textbf{DEDICATED} \\ \underline{\textbf{X}} & \textbf{FEDERAL} \end{array}$

<u>Summary of Legislation</u>: This bill prohibits administering a vaccine containing more than a trace amount of mercury to a person who is pregnant or less than eight years of age. The bill requires all other persons to be informed if a vaccine contains more than a trace amount of mercury. It also allows the Department of Health to suspend the requirement during a public health emergency or an epidemic.

The bill also provides that a health care practitioner may be subject to disciplinary sanctions for failing to comply with these requirements.

Effective Date: July 1, 2006.

<u>Explanation of State Expenditures:</u> Summary: The provisions of this bill would have minimal fiscal impact on the Department of Health since federal funds are used to purchase vaccines for local health departments and Vaccines For Children (VFC) program providers.

Children eligible for Medicaid receive federally funded vaccines under the VFC Program. If the VFC program supplies flu vaccines in the 2006-2007 flu season similar to the products offered in the current year, it is possible that the provisions of the bill would require an alternate funding source for vaccine to be found for the cohort of children ages 3 and 4 years. These children are too young to be administered the preservative-free alternatives of the nasal spray vaccine and too old for the thimerosal-free pediatric dose supplied by VFC.

The bill prohibits the administration of vaccine containing thimerosal to pregnant women. Medicaid-covered pregnant women now receive care under the capitated managed care contracts. The preservative status of

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vaccines administered by the Medicaid managed care organizations to pregnant women is not known. Any increases in cost due to the higher cost of thimerosal preservative-free vaccine would be dependent upon the number of women immunized for a flu season and would be expected to be minor in comparison to the total cost of maternity care.

Price differentials between vaccine products offered in the Vaccines for Children program are shown below.

Registered Brand Name or Trade Name	Contains Thimerosal	Packaging	CDC Cost per Dose	Private Sector Cost per Dose
Fluzone	Yes	10 dose vials	\$ 9.71	\$10.70
Fluzone Pediatric Dose	No	10, 1 dose syringes	\$12.02	\$13.00
FluMist	No	10, 1 dose sprayers	\$17.24	\$18.95 to \$19.95

Background Information: Thimerosal is an ethylmercury compound that has been used as a preservative in multi-dose vials of vaccine since the 1930s. Preservatives are not required for vaccines in single dose vials. The Centers for Disease Control (CDC) report that all routinely recommended licensed pediatric vaccines that are manufactured for the U.S. market, with the exception of influenza vaccine, contain no thimerosal or only trace amounts.

Influenza vaccine costs vary depending on the product and the packaging. Multi-dose vials containing thimerosal as a preservative are less expensive than individual dose syringes and the nasal spray influenza vaccines that do not contain thimerosal. The State Department of Health arranges for the purchase of vaccines, including influenza vaccine, under contracts negotiated by the CDC for local health departments using federal 317 Program funds. The Department also purchases vaccines for the children covered by Package C of Hoosier Healthwise (CHIP). These children are not covered by the Vaccines For Children entitlement. It is less costly for the Department to purchase the vaccine used in CHIP than it would cost to buy the products on the open market.

The remaining children are eligible for the federally funded Vaccines for Children program or are privately insured. The VFC entitlement program provides federally purchased vaccines for children from birth to age 18 who are enrolled in Medicaid, uninsured, or who are Native Americans. Children who have insurance that does not cover immunizations may receive VFC benefits at Federally Qualified Health Care Centers or rural health clinics. Private providers may also enroll in the VFC Program and administer vaccines to eligible children. The Department of Health supplies VFC vaccines to approximately 800 providers in the state.

Administration of influenza vaccine is encouraged for children 6 months of age and older by the Center for Disease Control's Advisory Committee on Immunization Practices. This recommendation, made in March 2003, was influenced by recent research that suggests that healthy children under the age of two years are more likely than older children and as likely as people over the age of 65 to be hospitalized with flu complications. The VFC program only offered thimerosal preservative-free vaccine for administration to children between 6 months to 36 months of age in the current contracts.

The bill provides that practitioners who fail to comply with the administration provisions or notification provisions of the bill are subject to disciplinary sanctions after a hearing by the appropriate board. The

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provisions of the bill could increase the number of hearings required of the licensing boards of practitioners that may administer vaccines. Sanctions a board may impose include: assessment of a fine not to exceed \$1,000; placing a practitioner on probationary status; issuing a letter of reprimand; censuring a practitioner; suspending a license; or permanently revoking a license.

Explanation of State Revenues:

Explanation of Local Expenditures: Local health departments immunize approximately 27% of Indiana's children against childhood diseases. The local health departments also provide influenza immunizations to children and adults. The State Department of Health reports that 86,780 doses of influenza vaccine have been ordered for the 2005-2006 flu season to be administered by public health departments or VFC providers. Approximately 41% of this vaccine is thimerosal preservative-free. Additionally, the State Department has ordered 6,230 doses of FluMist, the nasal spray vaccine for the VFC program. The number of children under the age of 8 years and pregnant women who receive vaccines containing thimerosal from the local health departments is unknown. Depending upon the number of at-risk children under the age of 8 and pregnant women the local health departments currently immunize, the fiscal impact of the provisions of the bill could potentially reduce the number of immunizations that the local departments could provide due to the higher cost of the preservative-free vaccine. However, this may be a temporary impact since manufacturers are phasing out the use of thimerosal in flu vaccines designated for the U.S. market.

The State Department of Health reports that some local health departments may also purchase additional flu vaccine outside the State Department's 317-funded program and the VFC program. The volume and type of vaccine purchased and the intended recipients are not known.

Explanation of Local Revenues:

State Agencies Affected: State Department of Health; Health Professions Bureau; Office of Medicaid Policy and Planning.

Local Agencies Affected: Local departments of health.

<u>Information Sources:</u> Centers for Disease Control and Prevention, "Questions & Answers: Thimerosol-Containing Influenza Vaccine" updated September 22, 2005, at http://www.cdc.gov/flu/qa/thimerosal.htm; and National Immunization Program (NIP), Vaccines for Children, CDC Vaccine Price List at http://www.cdc.gov/nip/vfc/cdc vac price list.htm

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